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VISTA BLOOD BANK SOFTWARE VERSION 5.2

1. **PURPOSE:** This Veterans Health Administration (VHA) Directive informs facilities that the Veterans Health Information Systems and Technology Architecture (*VISTA*) Blood Bank Software V5.2, also known as the Blood Bank module of the Decentralized Hospital Computer Program (DHCP) Laboratory package, has been submitted to the Food and Drug Administration (FDA) for registration as a medical device in accordance with the 1976, 1990 and 1992 Medical Device amendments to the Federal Food, Drug and Cosmetic Act (Public Law 75-717) and to provide guidance to VHA Information Resources Management (IRM) staff regarding local modifications. As part of the premarket submission required by Section 510(k), of the Federal Food Drug and Cosmetic Act, Title 21 United States Code (U.S.C.) Section 360(k), of the stringent change control procedures have been implemented for the blood bank software.

2. **BACKGROUND:** In 1994, FDA published a notice in the Federal Register indicating that blood bank software was considered a medical device and was therefore, subject to the portion of the Code of Federal Regulations devoted to medical devices, i.e., Parts 807, 820 and 821, as well as subject to good manufacturing practices and other FDA guidelines. On January 3, 1997, the Department of Veterans Affairs (VA) received an official warning regarding distribution of blood bank software which has not been officially approved by the FDA.

3. **POLICY**

a. Those components of a national package (routines, data dictionaries, etc.) that implement a controlled procedure, contains controlled or strictly defined interface or report data to a database external to the local facility, must not be altered except by the Chief Information Officer Field Office (CIOFO). The blood bank software provides significant design safeguards for safety critical requirements related to the safety, purity and potency of blood and blood components drawn and/or transfused in VHA facilities and, therefore, is subject strict change control procedures.

b. In accordance with M-2, Part VI, Chapter 5, paragraph 5.16, local modifications are the responsibility of the medical center and must meet all external requirements, including those set forth by the FDA, the College of American Pathologists (CAP) and the American Association of Blood Banks (AABB). All software changes must be thoroughly evaluated to determine the impact of the change on the intended uses, the safety critical requirements, the functional requirements and the software requirements specifications of the *VISTA* Blood Bank Software V5.2.

c. According to the FDA, if a facility makes local modifications in the blood bank software and intends to further distribute those modifications, that site must register as a device manufacturer and must provide a separate 510(k) summary for that version of the software.

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4. **ACTION**

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a. Veterans Integrated Service Network (VISN) Directors and VA medical center Directors are required to ensure that this policy is implemented.

b. The CIOFO which is responsible for development of this software has identified all of those components of the national Laboratory package which are impacted by this policy. Attachment A provides this listing. Routines shall have a statement embedded in the form of a comment which states that the routine contains controlled software, is subject to stringent change control procedures, and should not be modified. A similar comment must be included in the file description for files which are subject to this policy. Although routines and files currently in facilities do not include this comment, a conversion schedule will be established and disseminated once guidance is obtained from FDA.

c. The CIOFO will disseminate the listings of the intended uses, the safety critical requirements, the functional requirements and the software requirements specifications of the *VISTA* Blood Bank Software V5.2 to each site using the software for reference by the site when validating the software and when evaluating requests for local modifications.

d. For routines and files in Group A of the listing in Attachment A, local modifications are not to be made to the *VISTA* Blood Bank Software V5.2 except under the control of the Development CIOFO as change control is critical to the FDA good manufacturing requirements to which the software development process must adhere. In the event that local modifications are determined to be appropriate and required functionality cannot be provided through modification to the national package, consultation shall be obtained from the Blood Bank Developer and shall be documented by the site. Attachment B is a copy of the documentation done by the Blood Bank Developer for each patch and has been included as an example of the type of evaluation and documentation which is required.

e. For routines and files in Group B of the listing in Attachment A, local modifications may not be made without a formal evaluation to determine the potential impact on safety critical requirements of the *VISTA* Blood Bank Software V5.2 and to provide appropriate change control when indicated. Attachment B is a copy of the documentation done by the Blood Bank Developer for each patch and has been included as an example of the type of evaluation and documentation which is required.

f. For those sites who have already implemented and validated the *VISTA* Blood Bank Software V5.2, inclusive of Patch LR*5.2*72, installation of patches after LR*5.2*72 Sequence #98 shall be restricted to those which have been submitted to the FDA for approval and will involve a safety critical requirement. Information will be included in the patch description.

g. For those sites who are using *VISTA* Blood Bank Software V5.2, but have not yet installed Patch LR*5.2*72 as mandated for completion by December 31, 1996, plans must be made to expedite this implementation and validation testing as significant design safeguards were included for safety critical requirements, in addition to the multidivisional functionality.

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h. For those sites who have begun implementation and validation of *VISTA*, Blood Bank Software V5.2, but who have not yet eliminated parallel or manual systems, elimination of these systems must be delayed until after approval and/or clearance is received from the FDA.

i. For those sites which have not implemented any version of the *VISTA* Blood Bank Software V5.2, implementation and validation may be initiated in order to capture data for the Laboratory Management Index Program (LMIP); however, these sites cannot discontinue parallel or manual systems and rely solely on the computer until after approval and/or clearance is received from the FDA.

5. **REFERENCES**

a. Public Law 75-717, and 1976, 1990 and 1992 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act.

b. Title 21 U.S.C. Section 360.

c. Draft Reviewer Guidance for Premarket Notification Submission for Blood Establishment Computer Software, April 1996.

d. M-2, Part IV, Chapter 5.

e. Blood Bank Users Manual, *VISTA* Blood Bank software, V. 5.2.

6. **FOLLOW-UP RESPONSIBILITY:** The Chief Information Officer (19) and the Chief, Patient Care Services Officer (11) are responsible for the content of this Directive.

7. **RESCISSIONS:** This VHA Directive will expire on July 8, 2002.

S/ by Melinda Murphy for
Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

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ATTACHMENT A

VISTA COMPONENTS CONTAINING CONTROLLED SOFTWARE

1. Group A. Changes should not be made to the Blood Bank software except under the control of the Development Chief Information Officer Field Office (CIOFO).

- a. All options in the LRBL namespace
- b. All routines in the LRBL namespace
- c. Routines in the LRU namespace

LRUB	LRUD	LRUL	LRUT
LRUCN	LRUDIT	LRUMSG	

- d. Files

- (1) AGGLUTINATION STRENGTH (#62.55)
- (2) BLOOD INVENTORY (#65)
- (3) BLOOD BANK UTILITY (#65.4)
- (4) BLOOD DONOR (#65.5)
- (5) BLOOD PRODUCT (#66)
- (6) BLOOD VALIDATION (#66.2)
- (7) OPERATION (MSBOS) (#66.5)
- (8) BLOOD COMPONENT (#66.9)

2. Group B. Changes cannot be made without a formal evaluation to determine the potential impact on safety critical requirements and to provide appropriate change control when indicated.

NOTE: *The majority of the routines on the B list have been included because they relate to a patient specimen and evaluation of the acceptability of a patient specimen is a critical safety requirement and many design safeguards exist.*

- a. Routines in the LR namespace

LRCENDEL	LRU	LRUPA	LRUTW
LROS	LRUA	LRUPACA	LRUW
LRTSTJAM	LRUC	LRUPACT	LRUWG
LRTSTJAN	LRUFILE	LRUPT	LRUWK
LRTSTOUT	LRUG	LRUTL	LRUWL

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b. Files

- (1) LABORATORY TEST (#60)
- (2) FUNCTION FIELD (#61.3)
- (3) COLLECTION SAMPLE (#62)
- (4) EXECUTE CODE (#62.07)
- (5) LABORATORY DATA (#63)
- (6) LAB LETTER (#65.9)
- (7) ACCESSION (#68)
- (8) LAB SECTION PRINT (#69.2)
- (9) LABORATORY SITE (#69.9)

ATTACHMENT B

**SAMPLE FORMAT FOR
BLOOD BANK PATCH CHANGE CONTROL SUMMARY**

Patch # : _____

1. PRIORITY OF PATCH

☐ Patch to a patch ☐ Emergency ☐ Mandatory ☐ Informational

2. REASON FOR PATCH

- ☐ Installation of patch # _____ created an error at a site.
- ☐ Installation of patch # _____ inadvertently removed previous functionality.
- ☐ Functionality problem identified during site validation testing.
- ☐ Requested by a Laboratory package (non Blood Bank) developer Mailman message # _____.
- ☐ Requested by another package _____ Mailman message # _____.

3. CATEGORY OF PATCH (check all that apply)

- ☐ Routine(s)
- ☐ Input template(s)
- ☐ Print template(s)
- ☐ Option
- ☐ Data dictionary
- ☐ Documentation

4. REFERENCES

- ☐ National On-line information system (NOIS) #
- ☐ Electronic Error and Enhancement report (E3R) #
- ☐ Mailman message #

5. TEST SITES (including site(s) reporting problem):

<u>Name of Site</u>	<u>Hardware Platform</u>	<u>Operating System</u>
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6. **DESCRIPTION OF PROBLEM** (in sufficient detail to allow the user to recreate the scenario)

7. **RISK ANALYSIS** (based on prioritization schema)

_ HIGH: Impact on site(s) affected such that a blood component which might adversely affect a patient is released to inventory and/or transfusion or operations and/or services are interrupted or inaccurate data and/or reports are produced or change is necessary to meet new Department of Veterans Affairs (VA) reorganization and/or consolidations.

_ MODERATE: Impact on site(s) affected such that an option cannot be used or does not function and no work-around is available or change is necessary to meet new or existing regulation or change constitutes a major system quality improvement, e.g., electronic transmission of data through an interface instead of relying on manual data entry, or would result in significant cost savings.

_ LOW: New functionality which is needed or software does not function as intended or is misleading, but affects only a few sites or functionality which would be useful and affects many, if not all sites.

_ NONE: No impact on Blood Bank software functionality, however, changes necessary to ensure that background processing of data necessary for non-Blood Bank functional requirements, e.g., workload recording, HL7 messaging for data transfer, etc., continue with no loss of functionality when requirements change.

8. **IMPACT ON INTENDED USES (IU)**

_ Functionality included in IU # _____. No change in IU needed based on patch.
_ Functionality not included in the Intended Uses submitted to the Federal drug Administration (FDA). New IU needed # _____.

9. **IMPACT ON SOFTWARE REQUIREMENTS SPECIFICATIONS (SRS)**

_ Functionality included in SRS # _____. No change in SRS based on patch.
_ Functionality not included in the SRSs submitted to FDA. New SRS needed # _____.

10. **IMPACT ON SAFETY CRITICAL REQUIREMENTS (SCR)**

_ Change does NOT involve a safety critical requirement.
_ Functionality included in SCR # _____. No change in SCR based on patch.
_ Functionality not included in the listing of SCRs submitted to FDA. New SCR needed # _____.

11. **IMPACT ON FUNCTIONAL REQUIREMENTS**

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- ☐ Change does not involve a software design safeguard for a safety critical requirement.
- ☐ Change involves a software design safeguard, SRS # _____, for a safety critical requirement, SCR# _____, but does not change the scope of the SRS or the intended use IU # _____.
- ☐ Change involves a software design safeguard, SRS # _____, for a safety critical requirement, SCR# _____, and while it does not change the intended use, IU # _____, it does change the scope of the design safeguard (new SRS# _____).

12. IMPACT ON DOCUMENTATION (Blood Bank User Manual)

- ☐ No change in Blood Bank User Manual.
- ☐ Changes required in Blood Bank User Manual (specify page _____).

13. EVALUATION SUMMARY

- ☐ Patch documentation is complete and and/or or adequate (attach all documentation).
- ☐ Patch does not need to be submitted to the FDA for approval.
- ☐ Patch needs to be submitted to the FDA for approval before release.

Completed By _____